| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 01D0302673 | 12/15/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Oncology Specialties, Pc | 101 Dr W H Blake Jr Drive, Muscle Shoals, AL | |

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| **D2016** | SUCCESSFUL PARTICIPATION<br>CFR(s): 493.803(a)(b)(c)<br><br>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.<br><br>This CONDITION is not met as evidenced by:<br>Based on a review of CMS (Centers for Medicare and Medicaid Services) CASPER reports and MLE (Medical Laboratory Evaluation) Proficiency Testing (PT) reports, and telephone interviews with the laboratory staff, the surveyor determined the laboratory failed to successfully participate in proficiency testing for the WBC Differential (White Blood Cell Diff) for two of three consecutive testing events. These failures resulted in an initial unsuccessful PT participation. The findings include: 1. A review of the CASPER reports revealed the laboratory scored 60 percent (%) for the WBC Diffs for Events #1 and #3, 2021. 2. Further review of the MLE reports revealed the laboratory results for the automated differential (5-part diff via the Pentra 60C+) |

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| | were scored as N/A, (Not Applicable). 3. On 12/15/2021 at 8:45 AM, via a telephone call, testing personnel stated the laboratory normally reported out the automated diffs for patient specimens. This personnel member added that the laboratory supervisor needed to be consulted for further information, regarding the absence of reporting to MLE of the automated diff (primary method of testing Complete Blood Counts). 4. At 10:13 AM on 12/15/2021, via telephone interview, the laboratory supervisor stated the automated differentials were routinely reported on patient samples. Additionally, she stated the blood cell identification (which was reported and resulted in the failures) was what was set-up by the previous management. According to this supervisor, she has updated MLE for year 2022 (automated diffs will be performed and reported). The laboratory supervisor confirmed the laboratory staff did not report the automated diff for Events #1 and #3 of 2021, but read the pictures/graphs provided by MLE for the Blood Cell Identification and reported the results. Note: The laboratory must participate in PT using the primary method of testing, at the time of the PT event. |
| **D2130** | HEMATOLOGY<br>CFR(s): 493.851(f)<br><br>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of CMS (Centers for Medicare and Medicaid Services) CASPER reports and MLE (Medical Laboratory Evaluation) Proficiency Testing (PT) reports, and telephone interviews with the laboratory staff, the surveyor determined the laboratory failed to satisfactorily perform in proficiency testing for the WBC Differential (White Blood Cell Diff) for two of three consecutive testing events. These failures resulted in an initial unsuccessful PT participation (Refer to D2016). The findings include: 1. A review of the CASPER reports revealed the laboratory scored 60 percent (%) for the WBC Diffs for Events #1 and #3, 2021. 2. Further review of the MLE reports revealed the laboratory results for the automated differential (5-part diff via the Pentra 60C+) were scored as N/A, (Not Applicable). 3. On 12/15/2021 at 8:45 AM, via a telephone call, testing personnel stated the laboratory normally reported out the automated diffs for patient specimens. This personnel member added that the laboratory supervisor needed to be consulted for further information, regarding the absence of reporting to MLE of the automated diff (primary method of testing Complete Blood Counts). 4. At 10:13 AM on 12/15/2021, via telephone interview, the laboratory supervisor stated the automated differentials were routinely reported on patient samples. Additionally, she stated the blood cell identification (which was reported and resulted in the failures) was what was set-up by the previous management. According to this supervisor, she has updated MLE for year 2022 (automated diffs will be performed and reported). The laboratory supervisor confirmed the laboratory staff did not report the automated diff for Events #1 and #3 of 2021, but read the pictures/graphs provided by MLE for the Blood Cell Identification and reported the results. |